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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.	
09/827,812	04/06/2001	Daniel Lyon Pollard	0419-015	6862	
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Stein, McDermott, Will & Emery Mark B. Stein			GILLIGAN, CHRISTOPHER L		
28 State Stret			ART UNIT	PAPER NUMBER	
Boston, MA 02109-1775			3626		

DATE MAILED: 06/17/2005

Please find below and/or attached an Office communication concerning this application or proceeding.



	Application No.	Applicant(s)			
Office Action Commence	09/827,812	POLLARD ET AL.			
Office Action Summary	Examiner	Art Unit			
	Luke Gilligan	3626			
The MAILING DATE of this communication appearing for Reply	opears on the cover sheet with the c	correspondence address			
A SHORTENED STATUTORY PERIOD FOR REP THE MAILING DATE OF THIS COMMUNICATION - Extensions of time may be available under the provisions of 37 CFR 1 after SIX (6) MONTHS from the mailing date of this communication. - If the period for reply specified above is less than thirty (30) days, a re - If NO period for reply is specified above, the maximum statutory perio - Failure to reply within the set or extended period for reply will, by statu. Any reply received by the Office later than three months after the mail earned patent term adjustment. See 37 CFR 1.704(b).	.136(a). In no event, however, may a reply be tin ply within the statutory minimum of thirty (30) day d will apply and will expire SIX (6) MONTHS from tle, cause the application to become ABANDONE	nely filed s will be considered timely. the mailing date of this communication. D (35 U.S.C. § 133).			
Status					
1) Responsive to communication(s) filed on 06.	April 2001.				
3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is					
closed in accordance with the practice under	Ex parte Quayle, 1935 C.D. 11, 45	53 O.G. 213.			
Disposition of Claims					
4)⊠ Claim(s) <u>1-7</u> is/are pending in the application.					
4a) Of the above claim(s) is/are withdrawn from consideration.					
5) Claim(s) is/are allowed.					
6)⊠ Claim(s) <u>1-7</u> is/are rejected.					
7) Claim(s) is/are objected to.					
8) Claim(s) are subject to restriction and	or election requirement.				
Application Papers	•				
9)☐ The specification is objected to by the Examir	ner.				
10)☐ The drawing(s) filed on is/are: a)☐ accepted or b)☐ objected to by the Examiner.					
Applicant may not request that any objection to the	e drawing(s) be held in abeyance. See	e 37 CFR 1.85(a).			
Replacement drawing sheet(s) including the corre		• •			
11) The oath or declaration is objected to by the E	Examiner. Note the attached Office	Action or form PTO-152.			
Priority under 35 U.S.C. § 119					
 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: 1. Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No. 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). 					
* See the attached detailed Office action for a list of the certified copies not received.					
	it of the certained copies not receive	u.			
Attachment(s)					
Notice of References Cited (PTO-892)	4) Interview Summary				
2) \square Notice of Draftsperson's Patent Drawing Review (PTO-948) \bowtie Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08	Paper No(s)/Mail Da 5) Notice of Informal P	atent Application (PTO-152)			
Paper No(s)/Mail Date 6/11/01.10/15/01.10/15/02 6) Other:					

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Claims 1-7 have been examined.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

- 2. Claims 1-7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
- 3. Claim 1 recites the limitation "the machine-readable attributes" in lines 9-10. Because there are not previous recitations of "machine-readable attributes" of a specific sample, there is insufficient antecedent basis for this limitation in the claim. For examination purposes, the Examiner will disregard the term "the" preceding this recitation of "machine-readable attributes."
- 4. Claims 2-7 contain the same deficiencies as claim 1 through dependency and, as such, are rejected for the same reasons.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- 6. Claims are rejected under 35 U.S.C. 102(b) as being anticipated by Thornton, U.S. Patent No. 5,628,530.
- 7. As per claim 1, Thornton teaches a method for inclusion of information regarding medical samples into a medical information manager system, the method comprising: a)

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initiating an electronic session on a medical information manager device associated with the medical information manager system regarding an interaction between a health care provider and a particular patient (see column 2, lines 1-29, it should be noted that the Examiner is relying upon the electronic embodiment described in this reference and particularly shown in figures 2 and 3); b) using an input device associated with the medical information manager system to read into the medical information manager device machine-readable attributes of a specific sample of a particular product to be provided to the patient (see column 3, line 58 – column 4, line 9, note that the machine-readable attributes are those already contained on the smart card that is delivered to the physician, see column 5, lines 3-14); c) associating the machine readable attributes of the specific sample with a set of the particular patient's health records stored in the medical information manager system, the machine-readable attributes including a standard identification code for a particular product corresponding to the specific sample (see column 4, lines 19-28); d) use the machine-readable attributes of the specific sample to partially populate an electronic prescription form for the particular product matching the specific sample (see column 3, lines 37-46); and e) receive input through an input device connected to the medical information manager device from the health care provider to complete the partially populated prescription form (see column 3, lines 46-57).

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8. As per claim 3, Thornton teaches the method of claim 1 as described above. Thornton further teaches the machine readable attributes of a specific sample are read by reading a communication media selected from the group consisting of barcodes, magnetic strips, radio frequency broadcast, infra red transmission, and characters suitable for optical character recognition (see column 4, lines 2-9).

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Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

- (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 10. Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over Thornton, U.S. Patent No. 5,628,530 in view of Cunningham, U.S. Patent No. 6,055,507.
- 11. As per claim 2, Thornton teaches the method of claim 1 as described above. Thornton further teaches a record of the provision of the specific sample is stored for use in a program for tracking of samples (see column 2, lines 3-6). Thornton does not explicitly teach the machine-readable attributes of a specific sample include a lot number for the specific sample.

 Cunningham teaches a method for tracking drug sample distribution that includes recording machine-readable attributes of a specific sample that include a lot number (see column 5, lines 20-33, the Examiner is interpreting the "series of manufacturer I.D. numbers to incorporate a lot number). It would have been obvious to one of ordinary skill in the art at the time of the invention to incorporate this feature into the system of Thornton. One of ordinary skill in the art would have been motivated to incorporate this feature for the purpose of reducing costs associated with manufacturing by providing the same packaging with the same packaging information for samples as that of non-sample pharmaceutical products (see column 3, lines 61-67).
- 12. Claims 4-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Thornton, U.S. Patent No. 5,628,530 in view of Lester et al., U.S. Patent No. 6,021,392.

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13. As per claim 4. Thornton teaches the method of claim 1 as described above. Thornton does not explicitly teach reading machine-readable attributes from machine-readable medial on the container which holds packages of the specific samples. Lester teaches reading machine-readable attributes from machine-readable medial on a container which holds packages of the specific medication samples (see column 7, lines 19-43). It would have been obvious to one of ordinary skill in the art at the time of the invention to incorporate this feature into the system of Thornton. One of ordinary skill in the art would have been motivated to incorporate this feature for the purpose of enhancing the efficiency and accuracy of the data tracking within Thornton (see column 7, lines 46-54 of Lester).

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- 14. As per claim 5, Thornton teaches the method of claim 1 as described above. Thornton does not explicitly teach reading machine-readable attributes from machine-readable medial on the exterior packaging of the specific samples. Lester teaches reading machine-readable attributes from machine-readable medial on the exterior packaging of the specific medication samples (see column 8, lines 16-24). It would have been obvious to one of ordinary skill in the art at the time of the invention to incorporate this feature into the system of Thornton. One of ordinary skill in the art would have been motivated to incorporate this feature for the purpose of enhancing the efficiency and accuracy of the data tracking within Thornton (see column 7, lines 46-54 of Lester).
- 15. As per claim 6, Thornton teaches the method of claim 1 as described above. Thornton does not explicitly teach reading machine-readable attributes from a barcode on the particular product in the specific samples. Lester teaches reading machine-readable attributes from a barcode on the particular product in the specific medication samples (see column 7, lines 19-43). It would have been obvious to one of ordinary skill in the art at the time of the invention to incorporate this feature into the system of Thornton. One of ordinary skill in the art would have

been motivated to incorporate this feature for the purpose of enhancing the efficiency and accuracy of the data tracking within Thornton (see column 7, lines 46-54 of Lester).

- 16. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Thornton, U.S. Patent No. 5,628,530 in view of Dirbas, U.S. Patent No. 6,182,047.
- 17. As per claim 7, Thornton teaches the method of claim 1 as described above. Thornton does not explicitly teach inputting by reader associated with the medical information manager system a code indicating that the particular patient is to receive a medical order for medical services. Dirbas teaches teach inputting by reader associated with the medical information manager system a code indicating that the particular patient is to receive a medical order for medical services selected from the group consisting of laboratory tests, radiology tests, consults, medical procedures, follow-up appointments, and exercise programs (see column 6, lines 16-34). It would have been obvious to one of ordinary skill in the art at the time of the invention to incorporate this feature into the system of Thornton. One of ordinary skill in the art would have been motivated to incorporate the feature for the purpose of enhancing the ability to track additional information (other than what is already tracked by Thornton) related to medical services provided to patients (see column 2, lines 1-19 of Dirbas).

Conclusion

- 18. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.
 - Bootman et al. discloses a computer-based system for dispensing pharmaceutical samples.

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19. Any inquiry concerning this communication or earlier communications from the examiner

should be directed to Luke Gilligan whose telephone number is (571) 272-6770. The examiner

can normally be reached on Monday-Friday 8am-5:30pm.

20. If attempts to reach the examiner by telephone are unsuccessful, the examiner's

supervisor, Joseph Thomas can be reached on (571) 272-6776. The fax phone number for the

organization where this application or proceeding is assigned is 703-872-9306.

21. Information regarding the status of an application may be obtained from the Patent

Application Information Retrieval (PAIR) system. Status information for published applications

may be obtained from either Private PAIR or Public PAIR. Status information for unpublished

applications is available through Private PAIR only. For more information about the PAIR

system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private

PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

06/13/05

C. Luke Gilligan Patent Examiner Art Unit 3626